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APPLICATION	NO. F	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,767 03/26/2004		03/26/2004	Shudong Wang	CCI-029CN	9076
959	7590	06/29/2006		EXAMINER	
	E & COCKI TE STREET	FIELD	RAO, DEEPAK R		
BOSTON, MA 02109			ART UNIT	PAPER NUMBER	
				1624	
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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	10/810,767	WANG ET AL.				
Office Action Summary	Examiner	Art Unit				
	Deepak Rao	1624				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tirr vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	I. tely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 26 M	<u>arch 2004</u> .					
2a) This action is FINAL . 2b) ⊠ This	This action is FINAL . 2b)⊠ This action is non-final.					
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) Claim(s) 1-19 / 4a of the above claim(s) is/are withdraw 5) Claim(s) is/are allowed. 6) Claim(s) 1-19 / 4are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or	vn from consideration.					
Application Papers						
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the Replacement drawing sheet(s) including the correct and the correct of the co	epted or b) objected to by the led drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). lected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s)	_					
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date						
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 20041124.		ratent Application (PTO-152)				

DETAILED ACTION

Claims 1-19 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a proliferative disorder of the type disclosed in Table 3 (page 43 of the specification), does not reasonably provide enablement for a method of treating proliferative disorder generally. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed. The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations.

The instant claim 14 is drawn to 'a method of treating a proliferative disorder', however, it is not recited which proliferative disorders are included in the claim. The claim language covers any and all types of proliferative disorders and the specification on page 1 provides cancer, leukemia, psoriasis, as some of the diseases included here. The instant claims covers proliferative disorders that are known to exist and those that may be discovered in the future, for which there is no enablement provided.

Test assays and procedures using CDK2/cyclin E and CDK4/cyclin D1 containing cells are provided in the specification pages 38-40, related to the inhibition, and concluded that the compounds of the invention have CDK inhibitory activity as disclosed in Table 1 for some of the compounds of the invention, however, there is nothing in the disclosure regarding how this *in vitro* data correlates to the treatment of proliferative disorders of the instant claims. The instant method includes all types of proliferative disorders such as cancer, leukemia, etc. some of which have been proven to be extremely difficult to treat. Further, there is no reasonable basis for assuming that the myriad of compounds embraced by the claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same. Note *In re Surrey*, 151 USPQ 724 regarding sufficiency of disclosure for a Markush group.

Further, there is no disclosure regarding how the patient in need of such specific kinase inhibiting activity is identified and further, how types of proliferative diseases are treated. See MPEP § 2164.03 for enablement requirements in cases directed to structure-specific arts such as the pharmaceutical art. Receptor activity is generally unpredictable and highly structure specific area, and the data provided of the single compound is insufficient for one of ordinary skill in the

art in order to extrapolate to the other compounds of the claims. It is inconceivable as to how the claimed compounds can treat the extremely difficult diseases embraced by the instant claims. The state of the art is indicative of the unpredictability of the therapeutic approach based on kinase inhibiting activity. Regarding CDK mechanism, Blain et al. (J. of Biol. Chem.) report that "their specific functions are still poorly understood" (see page 25863, col. 1). Also, LuValle et al. (Frontiers in Bioscience) express that "detailed analyses of these pathways are necessary for a complete understanding of chondrocyte proliferation and differentiation" (see page 5, section 4). This is clearly indicative of the fact that the therapeutic role of these kinase inhibitors is very speculative.

The instant claims are drawn to 'a method of treating a proliferative disorder' and claim 15 specifically recites the proliferative disorder is cancer or leukemia. No compound has ever been found to treat proliferative disorders or cancers of all types generally. Since this assertion is contrary to what is known in medicine, proof must be provided that this revolutionary assertion has merits. The existence of such a "silver bullet" is contrary to our present understanding of oncology. Cecil Textbook of Medicine states that, "each specific type has unique biologic and clinical features that must be appreciated for proper diagnosis, treatment and study" (see the enclosed article, page 1004). A 'disease caused by proliferation of tumor cell' is anything that is caused by abnormal tissue growth. That can be growth by cellular proliferation more rapidly than normal, or continued growth after the stimulus that initiated the new growth has ceased, or lack (partial or complete) of structural organization and/or coordination with surrounding tissue. It can be benign or malignant. Thus, such term covers not only all cancers, but also covers precancerous conditions such as lumps, lesions, polyps, etc. Different types of

cancers affect different organs and have different methods of growth and harm to the body. Also see *In re Buting*, 163 USPQ 689 (CCPA 1969), wherein 'evidence involving a single compound and two types of cancer, was held insufficient to establish the utility of the claims directed to disparate types of cancers'. Thus, it is beyond the skill of oncologists today to get an agent to be effective against cancers or disorders caused by kinases generally.

Further, there is no established single antiproliferative therapeutic agent for all these types of diseases, which are characterized by the proliferation of tumor cells. The ideal chemotherapeutic drug would target and destroy only cancer cells without adverse effects or toxicities on normal cells. Unfortunately, no such drug exists; there is a narrow therapeutic index between cell kill of cancer cells and that of normal cells. Successful treatment of cancer requires elimination of all cancer cells, whether at the primary site, extended to local-regional areas, or metastatic to other regions of the body. The major modalities of therapy are surgery and radiotherapy (for local and local-regional disease) and chemotherapy (for systemic sites). For example, regarding the treatment of leukemia, The Merck Manual (online edition) states, that "Treatment programs and clinical situations are complex". Dosage regimen is dependent on several risk factors and the contribution of each active ingredient of a multidrug combination therapy is complex and unclear.

Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use of the instant compounds. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of

unpredictability of the factors involved". See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

(Only a few of the claimed diseases are discussed here to make the point of an insufficient disclosure, it does not definitely mean that the other diseases meet the enablement requirements). There is no evidence of record, which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the disease(s) or disorder(s) claimed herein.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

- 1) The nature of the invention: Therapeutic use of the compounds in treating a kinase mediated disease.
- 2) The state of the prior art: There are no known compounds of similar structure which have been demonstrated to treat patients suffering from all types of proliferative disorders. In reference to cancer treatment using protein tyrosine kinase inhibitors, Traxler (Exp. Opin. Ther. Patents, 1997) stated that 'pharmacological properties such as stability in biological media, bioavailability, metabolism or formulability are significant hurdles' see page 585, col. 2, lines 33-36.
- 3) The predictability or lack thereof in the art: Applicant has not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use of the instant

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compounds. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, 'the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved'. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

- 4) The amount of direction or guidance present and 5) the presence or absence of working examples: There are no doses present to direct one of ordinary skill in the art to use the compounds in the treatment of all of the diseases or disease symptoms within the scope of the claims. The specification provides (see pages 38-43) tests for the measurement of CDK2 and CDK4 kinase inhibitory activity of the compounds and IC₅₀ data for some of the compounds of the invention is provided. However, there is disclosure regarding how this data correlates to treatment of all types of proliferative disorders.
- 6) The breadth of the claims: The instant claims embrace inhibiting kinase activity in general and treating kinase mediated diseases in general.
- 7) The quantity of experimentation needed would be an undue burden, because it is not known what type of 'diseases' are referred to in the claims. Further, it would be an undue burden on one skilled in the pharmaceutical arts since there is inadequate guidance given to the skilled artisan, regarding the medical conditions or illnesses included in the instant claims.

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the use of the invention. In view of the breadth of the claim, the chemical nature of the invention, the unpredictability of ligand-receptor interactions in general, and the lack of working examples regarding the activity of the claimed compounds, one having ordinary skill in the art would have

to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- 1. Claim 12 recites the limitation "a compound according to claim 1 or claim 6, or a pharmaceutical salt thereof" in lines 1-2. There is insufficient antecedent basis for this limitation in claims 1 and claim 6 on which claim 12 is dependent. Claims 1 and 6 do not recite 'a pharmaceutically acceptable salt'. The discrepancy also appears in claims 14 and 19.
- 2. Claims 18-19 provide for the use of the compound, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

Claims 18-19 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for

example Ex parte Dunki, 153 USPQ 678 (Bd.App. 1967) and Clinical Products, Ltd. v. Brenner, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being obvious over Wang et al., WO 01/72745. The reference teaches a generic group of substituted 4-thiazolyl-2-phenyl-amion-pyrimidine compounds, which embraces applicant's instantly claimed compounds. See formula I in page 2 wherein one of X^1 and X^2 is S and the other is N; Z is NH and the preferred compounds in Figure 1. The compounds are taught to be useful as pharmaceutical agents having CDK inhibitory activity, see page 17. The instant claims differ from the reference by reciting specific

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species of the reference genus. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as therapeutic agents. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. *In re Susi*, 440 F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. v. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

Alternatively, the instantly claimed compounds are homologs of the reference compounds, i.e., they differ by a -CH₂ group from the reference disclosed compound. For example, see compound 76 in Fig 1, sheet 6/14, which has a -NH-CH₃ group as the substituent at the 2-position of the thiazolyl. The instantly claimed compound [44] in place contains a substituent -NH-CH₂-CH₃; and compound [52] contains a substituent -N(CH₃)₂. The above claimed compounds differ from the reference compounds by a -CH₂ group and it is well established that compounds that differ by a -CH₂ group are structural homologs. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the reference compounds to prepare the structural homolog. One having ordinary skill in the art would have been motivated to prepare the instantly claimed compounds because such structurally homologous compounds are expected to possess similar properties. It has been held

that compounds that are structurally homologous to prior art compounds are *prima facie* obvious, absent a showing of unexpected results. *In re Hass*, 60 USPQ 544 (CCPA 1944); *In re Henze*, 85 USPQ 261 (CCPA 1950).

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Tertiary versus secondary amines are homologues. Mono-substituted piperazines were found unpatentable over disubstituted piperazines in *Ex Parte Weston & Hamlin* 121 USPQ 428. It was stated "... any chemist is readily aware of the difference between secondary and tertiary amines, including their reactivities, particularly with respect to the possibility of further substitution for the H in the secondary amine." *Ex parte Bluestone*, 135 USPQ 199, and *In re Doebel*, 179 USPQ 158 further affirm that N-CH₃ is obvious over N-H. *In re Hoeksema*, 154 USPQ 169 in stating that secondary and primary amines are homologues state "...a chemist looking at the formula for another compound which differs so slightly that it is called a homolog generally expects the second compound to have properties similar to the first one."

Alternatively, the instant compounds differ from the reference compounds by being positional isomers. For example, see compound 113 in Fig. 1, sheet 9/14 wherein a 4-OH substituent is present on the phenyl group. The instantly claimed compound [13] on the other hand has a 3-OH substituent on the phenyl group. Therefore, the instantly claimed compounds are positional isomers of the reference compounds because they differ from the reference compounds by the position of a substituent. It would have been obvious to one having ordinary skill in the art at the time of the invention to prepare the instantly claimed compounds because they are positional isomers of the reference compounds. One having ordinary skill in the art would have been motivated to prepare the instantly claimed compounds because such isomeric compounds are suggestive of one another and would be expected to share similar properties and

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therefore, the same use as taught for the reference compounds, i.e., as pharmaceutical agents. It has been held that a compound, which is structurally isomeric with a compound of prior art is prima facie obvious absent unexpected results. *In re Finley*, 81 USPQ 383 (CCPA 1949); *In re Norris*, 84 USPQ 458 (CCPA 1950); *In re Dillon*, 919 F.2d at 696, 16 USPQ2d at 1904 (Fed. Cir. 1990).

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Note: Applicant cannot rely on the priority date of the foreign applications GB 0123377.4 (September 28, 2001) and GB 0123629.8 (October 2, 2001) to overcome the rejection because the priority application do not satisfy the enablement and description requirements of 35 U.S.C. 112, first paragraph for the instant claims. The priority documents do not support the all of the compounds of the instant claims.

2. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being obvious over Wang et al., 6,531,479 (effective filing date March 29, 2001).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in

the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

US'579 belongs to the same patent family as WO 01/72745 and the disclosure is identical, therefore, the reasons provided in rejection over WO'745 apply here.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See Miller v. Eagle Mfg. Co., 151 U.S. 186 (1894); In re Ockert, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer <u>cannot</u> overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-19 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-19 of copending Application No. 11/433,312. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,531,479. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed compounds are encompassed by genus of the reference. See the reasons provided under 35 U.S.C. 103 rejection above.

Receipt is acknowledged of the Information Disclosure Statement filed on November 24, 2004 and a copy is enclosed herewith.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deepak Rao Primary Examiner Art Unit 1624

June 26, 2006